UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

MDL No. 01-1396 (JRT/FLN)

IN RE: ST. JUDE MEDICAL, INC. SILZONE HEART VALVES PRODUCTS LIABILITY LITIGATION

MEMORDANDUM OPINION AND ORDER

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This memorandum opinion and order addresses four outstanding motions that have been fully briefed and argued. The Court first addresses St. Jude Medical's ("St. Jude") request for permission to file an interlocutory appeal, and then turns to St. Jude's motion to decertify the consumer fraud class. Next, the Court addresses plaintiffs' motion to redefine the "injury class" that the Court previously certified. Finally, the Court briefly addresses St. Jude Medical's motion to stay the issuance of the class notice. For the

reasons discussed below, the Court grants in part plaintiffs' motion, and denies all of St. Jude's motions.

BACKGROUND

The Court is intimately familiar with the background of this dispute, and will provide only the following summary. More specific factual information will be addressed where such information is relevant to the particular motion.

I. Factual Background

Defendant St. Jude manufactures a variety of medical devices including the "Silzone" heart valve. The Silzone valve has a coating of silver on the sewing cuff, the part of the valve that is sewn to the patient's body. Silver was added to the valve because of its potential anti-microbial properties, which was hoped would combat endocarditis, a potentially life-threatening infection of the cardiac tissue that is a possible consequence of prosthetic heart valve implantation.

The Silzone valve was approved for commercial distribution on March 24, 1998. As part of this approval, however, the FDA prohibited St. Jude from claiming that the Silzone coating would reduce the risk of endocarditis. After the FDA approved the Silzone valve, St. Jude sponsored the Artificial Valve Endocarditis Reduction Trial ("AVERT") study, a multi-national clinical trial designed to study whether the Silzone-coated heart valve reduced the incidence of endocarditis in humans. AVERT was originally intended to involve 4,400 heart valve patients, out of approximately 36,000 patients who have been implanted with the valve worldwide. The study enrolled only

792 patients; approximately half of whom received Silzone-coated valves and another half, the control group, received conventional (non-Silzone) valves. The results of AVERT are reviewed by an independent monitoring board.

In January 2000, the AVERT monitoring board reported that recipients of the Silzone valve were more likely to experience a complication called paravalvular leak,[1] requiring the prosthetic valve to be removed and replaced with another valve, compared to recipients of conventional valves. On January 21, 2000, the monitoring board suspended enrollment in the AVERT trial because of this increase in paravalvular leak.[2] On the same day, St. Jude voluntarily recalled all un-implanted Silzone products. As part of the recall, St. Jude immediately notified hospitals and physicians, instructing them not to use Silzone products. St. Jude also sent letters regarding the care and management of patients with implanted Silzone valves, and established a reimbursement program to pay for uninsured medical costs associated with the detection, diagnosis, and treatment of paravalvular leak.

II. Procedural History

On April 18, 2001, the cases comprising this multidistrict litigation were transferred to this Court by the Judicial Panel on Multidistrict Litigation for consolidated

[1] Paravalvular leak involves leakage at the point where a heart valve is sutured to a patient's tissue.

[2] Although enrollment in AVERT was suspended, the participants continue to be monitored, and data are still collected and studied.

pretrial proceedings under 28 U.S.C. § 1407. The Court has issued several orders, three of which are relevant to the instant dispute.

On March 27, 2003, the Court issued an Order on plaintiffs' request for class certification. The Court found that the classes proposed by plaintiffs met the threshold requirements of Rule 23(a), that common issues of law and fact predominated, and that a class action was likely the superior method of adjudicating the claims. The Court conditionally certified plaintiffs' common law claims for both Class I (the monitoring class) and Class II (the injury class) pursuant to Rule 23(b)(3) and (c)(4). The Court also conditionally certified the medical monitoring claims of the Class I plaintiffs, pursuant to Rule 23(b)(2). Finally, the Court determined that common issues of law and fact predominated in plaintiffs' claims under Minnesota's consumer protection and deceptive trade practices acts and that a class action was the superior method of adjudicating those claims. The Court unconditionally certified plaintiffs' claims under those statutes pursuant to Rule 23(b)(3).

On January 5, 2004, the Court issued an Order addressing the subclass issue. In this Opinion and Order, the Court determined that Class II, the injury class, did not meet the requirements of Rule 23, and the Court decertified the injury class. The Court conditionally certified Class I, the monitoring class, contingent upon the plaintiffs' identification of adequate class representatives and plaintiffs' submission to the Court of a manageable trial plan.

Also issued on January 5, 2004, was the Court's Order denying St. Jude's motion for summary judgment on the ground of preemption. The Court's denial rested on its

analysis of controlling law, including the Eighth Circuit's decision in *Brooks v. Howmedica*, 273 F.3d 785, 795 (8th Cir. 2001), *cert. denied*, 535 U.S. 1056 (2002), as well as the Court's conclusion that material issues of disputed fact precluded a grant of summary judgment. The Court's decision acknowledged, but did not resolve, other arguments raised by plaintiffs in opposition to the motion for summary judgment, such as whether the Silzone valve retained approval, and whether the valve was appropriately considered a device, or whether it was a drug/device combination.

ANALYSIS

I. St. Jude's Motion for Permission to File an Interlocutory Appeal

As noted, the January 5, 2004 Opinion and Order denied St. Jude's motion for summary judgment on the ground of preemption. The Court determined that genuine issues of fact precluded the Court from granting summary judgment to defendant. St. Jude now requests permission to file an interlocutory appeal pursuant to 28 U.S.C. § 1292(b), which permits a district judge to certify for immediate appeal an order if, in the Court's opinion, "such order involves a controlling question of law as to which there is substantial ground for difference of opinion and that an immediate appeal from the order may materially advance the ultimate termination of the litigation." The Court of Appeals, in its discretion, then has immediate jurisdiction over the appeal. *Id.*

Orders permitting interlocutory appeal are appropriate only when each of the three criteria is satisfied. That is, the party requesting permission to file an interlocutory appeal must demonstrate that the order involves a controlling question of law, and that there is

substantial ground for difference of opinion on that question of law. Permission should not be granted unless the district court is satisfied that an immediate appeal may materially advance the ultimate termination of the litigation.

Those criteria are not satisfied here. The Court agrees with defendant's argument that the defense of preemption presents important policy implications, and in its January 5, 2004 Order, the Court recognized the difficulty presented by the arguments raised. However, the Court finally rested its decision on rather narrow, and uncontroversial, grounds – specifically, the Court determined that fact issues precluded summary judgment on each of the causes of action that the parties briefed. The determination that disputed issues of fact preclude a grant of summary judgment can hardly be considered a controlling question of law on which there is a substantial difference of opinion.

The Court declines to amend its January 5, 2004 Order to certify the preemption issue for immediate appeal.

II. St. Jude's Motion to Decertify the Consumer Fraud Class

The Court addressed plaintiffs' consumer fraud class in the Opinion and Order dated March 27, 2003 in which the Court certified plaintiffs' consumer fraud claims pursuant to Rule 23(b)(3). The Court determined that "common issues of law and fact predominate . . . and that a class action is the superior method of adjudicating those claims." March 27, 2003 Opinion and Order at 40. The Court's next order on subclass certification reiterated that the consumer fraud class would remain certified.

St. Jude now moves to decertify the class, making two primary arguments. First, St. Jude argues that Minnesota's consumer protection statutes cannot support plaintiffs' proposed nationwide class action. As its second argument, defendant suggests that the certified class satisfies neither Rule 23 nor the Constitution. The Court permitted St. Jude to file this motion to decertify, and the Court has a continuing duty to ensure that the class meets the requirements of Rule 23 and the Constitution. The Court advised counsel for defendant, however, that the Court would view a motion to decertify with skepticism, especially when the motion was filed nearly one year after the class was certified.

After reviewing St. Jude's submissions, the Court is satisfied that the original decision to certify is sound, and the Court will not decertify the consumer protection class. St. Jude does not raise new arguments, and the Court will not repeat its analysis of the consumer fraud law. The Court notes, however, that a recent Minnesota case further supports the Court's determination that class treatment is appropriate. *See Peterson v. BASF Corp.*, 675 N.W.2d 57 (Minn. 2004); *see also In re Lutheran Brotherhood Variable Ins. Prods. Co. Sales Practices Litig.*, 2004 WL 909741 (D. Minn. April 28, 2004).

III. Plaintiff's Motion for Reconsideration of Predicate Injury Required for Medical Monitoring Claims

Two issues are presented in this motion. The first is plaintiffs' request to include several jurisdictions that the Court previously excluded. St. Jude also argues for the exclusion of several states that the Court initially included in the class.

The Court, in its January 5, 2004 Order regarding subclasses, determined that the medical monitoring class would include only those individuals whose valves were implanted in jurisdictions recognizing medical monitoring claims as stand-alone causes of action absent proof of injury. The Court also held that individuals whose valves were implanted in jurisdictions that require the existence of a personal injury as a predicate to recovering medical monitoring costs would not be part of the certified medial monitoring class. Individuals with manifest injuries were excluded from the class entirely, regardless of where their valves were implanted. By so defining the class, the Court excluded individuals with injuries, because the Court was not satisfied that a sub-class of injured individuals satisfies the cohesiveness requirement of the Rule. In addition, the Court determined that plaintiffs with injuries would be more likely to pursue their claims as those claims are less likely to be "negative value" claims.

Plaintiffs have moved for reconsideration, arguing that the Court erred in limiting the class to those individuals whose valves were implanted in jurisdictions that do not require proof of injury. Plaintiffs suggest that they have presented expert testimony that each individual with a Silzone valve has at least a subcellular injury, and that such an injury is sufficient to meet the injury required by the jurisdictions that were excluded by the prior order. Plaintiffs conclude that every individual who has a Silzone valve implanted has sustained an injury, at least for purposes of medical screening and monitoring claims.

St. Jude opposes the motion for reconsideration, and also suggests that the Court erred in including some states in the class. St. Jude proposes that Colorado, Kansas,

Connecticut, the District of Columbia, Texas, Montana, and New York should be excluded from the class.[3]

The Court is persuaded, to some extent, by plaintiffs' renewed argument. The Court's decision to exclude individuals whose valves were implanted in "injury required" states represented an attempt to reduce or eliminate conflict of law issues, and as far as possible, to avoid lengthy efforts to prove the extent and causation of an individual's injuries. To the extent that plaintiffs have shown that there is only one overarching "causation" issue, the Court's concern on that basis is alleviated. However, the Court's decision to exclude certain states also rested, of course, on that state's treatment of medical monitoring claims. Plaintiffs urge that most jurisdictions that require an injury as a predicate to recovery of medical monitoring or medical screening costs hold that such predicate injury does not have to be a severe or profound one. Plaintiffs then go on to cite cases from numerous jurisdictions. Absent from this string cite, however, is explicit citation to, and explanation of, cases from most of the states which the Court excluded for being "injury required" states.[4]

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[3] St. Jude also suggests the Court should exclude Tennessee from the class. Tennessee was erroneously included in two classifications in the prior order, and plaintiffs agree that Tennessee should be included in the injury-requiring states. *See* Pls.' Reply to Summ. J. Mem. Opp'n to Pls.' Mot. for Recons. at 12 n.15.

[4] Specifically, the Court excluded Alabama, Delaware, Kentucky, Louisiana, Michigan, Minnesota, Missouri, Nevada, North Carolina, Ohio, Tennessee, Virginia, the Virgin Islands, and Washington on the basis that these states required injury as a predicate to a medical monitoring action. Of these fourteen jurisdictions, plaintiffs provide citation to decisions applying laws of Minnesota (*Werlein v. United States*, 746 F. Supp. 887, 901 (D. Minn. 1990), *vacated in part on other grounds*, 793 F. Supp. 898 (D. Minn. 1992); *Bryson v. Pillsbury Co.*, 573 N.W.2d 718,

(Footnote continued on next page.)

Nonetheless, the Court is persuaded that three states, Delaware, Minnesota, and Ohio, can be included in the class, as a separate subclass. The Court is persuaded that adding these three states will not raise cumbersome issues of causation and will not raise insurmountable conflict of laws issues. Specifically, Delaware is added based on the Court's revised analysis of the Delaware Supreme Court's decision in *Mergenthaler v. Asbestos Corp.*, 480 A.2d 647, 651 (Del. 1984). In *Mergenthaler*, the Court noted that asbestos-exposure plaintiffs must show a physical injury before a medical surveillance claim could be pursued. These particular plaintiffs, who were spouses of asbestos workers, could not pursue a medical monitoring claim because they had not demonstrated that they inhaled asbestos fibers, even though they had laundered the clothing of their asbestos-exposed spouses. *Id.* at 651. The Court noted that these plaintiffs were unlike those in *Ayers v. Jackson Twp.*, 461 A.2d 184 (N.J. 1983), because the *Ayers* plaintiffs had "actually ingested" contaminated well-water. *Id.* This case presents facts much more analogous to *Ayers* – each plaintiff "actually ingested" the Silzone valve when the valve was implanted. The Court therefore finds it appropriate to include individuals whose valves were implanted in Delaware.

The Court will also include individuals whose valves were implanted in Minnesota. This decision is premised on the Minnesota Court of Appeals determination in *Bryson v. Pillsbury*, 573 N.W.2d 718, 721 (Minn. Ct. App. 1998), that allegations of

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(Footnote continued.)

720-21 (Minn. Ct. App. 1998)) and Ohio (*Verbryke v. Owens-Corning Fiberglas Corp*, 616 N.E.2d 1162 (Ohio Ct. App. 1992)).

chromosome damage presented a fact question for the jury on whether an individual was "injured." As applied in the instant case, the proof of the alleged subcellular injury will be uniform across the class. Therefore, the inclusion of individuals whose valves were implanted in Minnesota does not raise individual issues of injury, and comports with the decision of the Minnesota Court of Appeals in *Bryson*. Finally, and for similar reasons, the Court includes individuals whose valves were implanted in Ohio. *Verbryke v. Owens-Corning Fiberglass Corp.*, 616 N.E.2d 1162 (Ohio Ct. App. 1992).

The remaining states, including Tennessee, will not be added. The Court declines to include those particular states because the Court's examination of the decisions and laws of those states does not support a determination that the subcellular injury is adequate to satisfy the injury requirement.

Next, the Court will address defendant's argument that several states were improperly included in the class. As noted above, St. Jude proposes that Colorado, Kansas, Connecticut, the District of Columbia, Texas, Montana, and New York should be excluded from the class. The Court declines to exclude any of the aforementioned states. The Court, in predicting the law of each state, undertook a proper *Erie*-analysis[5] and considered relevant information, including trial court opinions, opinions of federal courts interpreting the relevant state law, and opinions from states' intermediate appellate courts. The Court agrees with defendant that it is not the role of federal courts to blaze new trails of state law. At the same time, however, the Court cannot abdicate its

[5] *Erie R.R. Co. v. Tompkins*, 304 U.S. 78 (1938).

responsibility to predict, from all the available data, how a state's highest court would resolve the issue. Where the Court had some available data from a state – be it from state trial courts, state appellate courts, or federal courts – the Court used that data to predict the state law. In several states, the Court determined, from all the available data, that the state would not recognize medical monitoring as a stand alone claim. *See* January 5, 2004 Order at 21-23 (addressing states that either had not addressed medical monitoring, or had done so and rejected the claim). In other instances, the Court determined that it had adequate data to predict how the state's highest court would resolve the issue. *Id.* at 14-21.

In conclusion, at this time, the Court will consider Delaware, Minnesota, and Ohio plaintiffs to present a subclass of the medical monitoring class. However, this distinction may be more formalistic than practical, as the Court anticipates little or no difference in the required proof for this subclass and the subclass of states including Arizona, Colorado, Connecticut, District of Columbia, Florida, Illinois, Kansas, Montana, New Jersey, New York, Pennsylvania, Texas, Utah, and West Virginia.

IV. St. Jude's Motion to Stay the Class Notice

St. Jude requested that the Court defer ruling on the content and form of any proposed class notice until the conclusion of the pending decertification and reconsideration proceedings. The issuance of this Order renders that rationale for the stay moot, and the Court will therefore deny the motion. The Court orders the parties, within 15 days of the date of this Order, to meet and confer in a good faith effort to resolve their

disagreements regarding the content of the class notice in light of this Opinion and Order. The parties shall submit a joint report to the Court within 10 days of their meet and confer to update the Court as to the status of the class notice.

ORDER

Based upon the foregoing, the submissions of the parties, the arguments of counsel and the entire file and proceedings herein, **IT IS HEREBY ORDERED:**

1. Defendant's Motion for Permission to File an Interlocutory Appeal [Docket No. 289] is **DENIED**;

2. Defendant's Motion to Decertify Consumer Fraud Class [Docket No. 279] is **DENIED**;

3. Plaintiffs' Motion for Reconsideration of Decertification of Predicate Injury Required for Medical Monitoring Subclass [Docket No. 269] is **GRANTED to the extent plaintiffs seek a subclass including Delaware, Minnesota, and Ohio.** In all other respects, the motion is **DENIED.**

4. Defendant's Motion for a Stay [Docket No. 294] is **DENIED as moot.**

DATED: July 15, 2004
at Minneapolis, Minnesota.

s/ John R. Tunheim
JOHN R. TUNHEIM
United States District Judge